

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE

MEDICAL MUTUAL OF OHIO, INC.,)	
on behalf of itself and all others)	
similarly situated,)	
)	
Plaintiffs,)	
)	
v.)	Civ. No. 10-604-SLR
)	
BRAINTREE LABORATORIES,)	
)	
Defendant.)	

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MEMORANDUM OPINION

Dated: July 12, 2011
Wilmington, Delaware


ROBINSON, District Judge

I. INTRODUCTION

This is an antitrust action arising out of a patent infringement case filed on May 16, 2003 by Braintree Laboratories, Inc. (“Braintree”), a pharmaceutical company selling the constipation drug polyethylene glycol 3350 (“PEG”) in the United States under the brand name MiraLax®, against a generic drug manufacturer, Schwarz Pharma, Inc. (“Schwarz”), in which Braintree sought to preclude FDA approval for Schwarz’s generic PEG drug GlycoLax®. (Civ. No. 03-477-SLR (hereinafter, “the Braintree/Schwarz litigation”)) The Braintree/Schwarz litigation commenced when Braintree brought suit pursuant to 35 U.S.C. § 271(e)(2)(A)¹ responsive to Schwarz’s filing of an ANDA containing a “Paragraph IV” certification² claiming that the patent listed by Braintree in the FDA’s Orange Book³ as covering MiraLax®, U.S. Patent 5,710,183 (“the ‘183 patent” or the “Halow patent”), was invalid or not infringed by the manufacture, use, or sale of GlycoLax®. That suit triggered the 30-month stay on the FDA’s approval of Schwarz’s ANDA. See 21 U.S.C. § 355(j)(5)(B)(iii). The Braintree/Schwarz litigation was voluntarily dismissed by Braintree on June 3, 2004. Braintree waived any remaining portion of the 30-month stay, and GlycoLax® entered the market shortly the

¹“(2) It shall be an act of infringement to submit – (A) an application under section 505(j) of the Federal Food, Drug, and Cosmetic Act or described in section 505(b)(2) of such Act for a drug claimed in a patent or the use of which is claimed in a patent[.]”

²See 21 U.S.C. § 355(j)(2)(A)(vii)(IV).

³The FDA publishes patent information on approved drug products in its publication entitled “Approved Drug Products with Therapeutic Equivalence Evaluations,” commonly referred to as the “Orange Book,” a register that provides notice of patents covering name brand drugs.

FDA issued its approval on July 2, 2004. Medical Mutual of Ohio, Inc. ("MMOH") filed the instant putative class action against Braintree on July 14, 2010, alleging that the Braintree/Schwarz litigation was sham litigation designed to delay the FDA's approval of GlycoLax® and to improperly maintain Braintree's monopoly power on MiraLax®'s. (D.I. 1) In lieu of an answer, Braintree filed a motion to dismiss pursuant to Federal Rule of Civil Procedure 12(b)(6). (D.I. 10) For the reasons that follow, Braintree's motion is granted.

II. BACKGROUND

A. Procedural History

The Braintree/Schwarz litigation, with which the court presumes familiarity, was filed in 2003 and concluded in July 2008. (Civ. No. 03-477) In short, the facts of that case were as follows. Braintree discovered the '183 patent during a literature search while its NDA was pending with the FDA. It corresponded with the owner and iterated its position that the '183 patent was invalid as anticipated. Braintree succeeded in acquiring an exclusive license to the '183 patent for \$15,000, whereupon it listed the '183 patent in the Orange Book (in 1999) and later sued Schwarz for infringement based on Schwarz's ANDA. Braintree acquired the '183 patent outright (in 2001). During litigation, the inventor of the '183 patent (Dr. Halow) was deposed for the first time, during which he testified that the clinical trials for MiraLax® were not done under confidentiality agreements. The Federal Circuit law at that time (in 2004) provided that such trials could be used as § 102 anticipatory prior art.⁴ Braintree dismissed its suit on

⁴See *Baxter Int'l, Inc. v. Cobe Labs., Inc.*, 88 F.3d 1054, 1058 (Fed. Cir. 1996); compare *Bernhardt, L.L.C. v. Collezione Europa USA, Inc.*, 386 F.3d 1371 (Fed. Cir.

May 27, 2004,⁵ granted Schwarz a free license, waived the rest of the 30-month stay, and generic approval soon followed on June 2, 2004. Schwarz's generic PEG product, GlycoLax®, hit the United States market on or about July 8, 2004. (Civ. No. 03-477, D.I. 262 at ¶ 19)

Schwarz maintained its counterclaims of unfair competition, "tortious interference with business advantage/opportunities," and actual or attempted monopolization of the market for PEG laxatives in the United States in violation of the Sherman Act, 15 U.S.C. § 2. After a bench trial, the court found that Schwarz did not meet its high burden of proof to demonstrate that the sham litigation exception to Noerr-Pennington immunity applied. (*Id.* at ¶ 38⁶) Specifically, Braintree advanced a colorable claim construction under which its claims would be valid. Although not entirely consistent with its infringement position, the court determined that Braintree's position was not frivolous, and entered judgment for Braintree. (*Id.*)

Thereafter, a class action litigation was filed by drug wholesalers (direct purchaser plaintiffs, hereinafter "DPPs") on March 12, 2007. (Civ. No. 07-142 (hereinafter the "direct purchaser litigation")) DPPs brought a claim for a violation of the Sherman Act based on Braintree's improper maintenance of its monopoly on MiraLax® which, DPPs allege, resulted in artificially inflated prices on their PEG purchases. (Civ.

2004) (absence of confidentiality agreements not dispositive on issue of § 102(b) public use).

⁵(Civ. No. 03-477, D.I. 61) The court granted Braintree's motion for voluntary dismissal on June 3, 2004.

⁶Reported as *Braintree Labs., Inc. v. Schwarz Pharma, Inc.*, 568 F. Supp. 2d 487 (D. Del. 2008).

No. 07-142, D.I. 21 at ¶ 104) In denying Braintree's motion to dismiss, the court found that: (1) DPPs stated a claim for antitrust injury, which could properly be forged as an "overall scheme" to forestall competition; (2) DPPs have alleged facts supporting their claim for objective baselessness; (3) DPPs may make their own record, and succeed where Schwarz did not; and (4) the prior holding has no estoppel effect, as it was premised on Schwarz's failure to meet its high burden of proof, i.e., Braintree did not obtain a judgment of non-baselessness. (*Id.*, D.I. 27⁷) Following Braintree's termination of DPPs as authorized wholesalers per its agreements with Group Purchasing Organizations ("GPOs"), the court recently granted DPPs' motion for an injunction *pendente lite* and ordered Braintree to restore DPPs as customers upon the posting of a bond. (*Id.*, D.I. 145, 146)

Following the filing of the direct purchaser litigation in March 2007, a second antitrust action was filed on April 11, 2007, this time by the Philadelphia Federation of Teachers Health and Welfare ("PFTH&W") in the United States District Court for the District of Massachusetts. (D. Mass. Civ. No. 07-10704) PFTH&W's putative class action (hereinafter, the "PFTH&W litigation") was filed on behalf of indirect purchasers of MiraLax® who, PFTH&W alleged, paid higher prices for MiraLax® than they would have paid for generic PEG. The PFTH&W litigation was transferred to this court on June 6, 2007 and, after the court's decision in the Braintree/Schwarz litigation, PFTH&W voluntarily dismissed the case on June 2, 2009. (D. Del. Civ. No. 07-356, D.I. 21)

⁷Reported as *Rochester Drug Co-Operative, Inc. v. Braintree Labs.*, 712 F. Supp. 2d 308 (D. Del. 2010).

B. The Current Suit

MMOH brings this class action on behalf of the following class of indirect purchasers of MiraLax®:

All persons and entities in the United States and U.S. territories, who **from December 23, 2003**, until the effects of defendant's anticompetitive conduct cease (the "Class Period"), indirectly purchased, paid for and/or reimbursed for MiraLax® and/or any generic version thereof for consumption by their members, employees, insureds, participants or beneficiaries, and as to whom law or equity affords a claim upon which relief can be granted. Excluded from the Class are Defendant and its parents, employees, subsidiaries, and affiliates.

(D.I. 1, ¶ 16) (emphasis added) Plaintiffs allege that, as a result of Braintree's maintenance of the Braintree/Schwarz litigation, they were denied the benefits of unrestrained competition in the PEG market, that is, they were denied the opportunity to choose between MiraLax® and generic versions which would have been priced lower.

(*Id.* at ¶¶ 10-11)

The instant action was filed by MMOH on July 14, 2010, more than six years after the Braintree/Schwarz litigation was dismissed and GlycoLax® was introduced for sale, but within 60 days of this court's order denying Braintree's motion to dismiss the direct purchaser litigation. MMOH alleges in its complaint that Braintree unlawfully extended its monopoly power in the PEG market in violation of the antitrust laws of the states of Alabama, Arizona, California, Iowa, Kansas, Michigan, Mississippi, Nevada, New York, North Carolina, Tennessee, West Virginia, Wisconsin and the laws of the District of Columbia. (D.I. 1⁸ at ¶¶ 96-112) MMOH also brings claims under the state consumer fraud and unjust enrichment laws of Arizona, Arkansas, California, Colorado,

⁸All docket numbers hereinafter reference Civ. No. 10-604, unless specifically noted.

Connecticut, Florida, Georgia, Illinois, Kansas, Kentucky, Maryland, Michigan, Missouri, Nevada, New York, North Carolina, Ohio, Oklahoma, Oregon, Pennsylvania, South Carolina, Tennessee, Texas, Utah, Virginia, Washington, West Virginia and the laws of the District of Columbia. (*Id.* at ¶¶ 115-142)

III. STANDARD

In reviewing a motion filed under Federal Rule of Civil Procedure 12(b)(6), the court must accept all factual allegations in a complaint as true and take them in the light most favorable to plaintiff. See *Erickson v. Pardus*, 551 U.S. 89, 127 S.Ct. 2197, 2200 (2007); *Christopher v. Harbury*, 536 U.S. 403, 406 (2002). A complaint must contain “a short and plain statement of the claim showing that the pleader is entitled to relief, in order to give the defendant fair notice of what the . . . claim is and the grounds upon which it rests.” *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 127 S.Ct. 1955, 1964 (2007) (hereinafter, “*Twombly*”) (interpreting Fed. R. Civ. P. 8(a)) (internal quotations omitted). A complaint does not need detailed factual allegations; however, “a plaintiff’s obligation to provide the ‘grounds’ of his ‘entitle[ment] to relief requires more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do.” *Id.* at 1964-65 (alteration in original) (citation omitted). The “[f]actual allegations must be enough to raise a right to relief above the speculative level on the assumption that all of the complaint’s allegations are true.” *Id.* at 1959.

IV. DISCUSSION

A. Accrual of Claims

In order to address Braintree’s claims that this suit is time-barred, the court must

first determine the accrual date for purpose of tolling the statute of limitations. MMOH argues that the **earliest** its claims accrued was on June 3, 2004 – the date the court granted Braintree’s motion to dismiss its claims against Schwarz – because an “antitrust claim related to baseless litigation can only be determined upon the termination of the initial action.” (D.I. 13 at 9, 12 (citing *Chemi SpA v. GlaxoSmithKline*, 356 F. Supp. 2d 495, 500 (E.D. Pa. 2005)) The court disagrees.

A sham litigation counterclaim is compulsory where it “generally involve[s] the same factual issues as those involved in the patent infringement litigation between the same parties.” See *Critical-Vac Filtration Corp. v. Minuteman Int’l, Inc.*, 233 F.3d 697, 703 (2d Cir. 2000). Schwarz’s sham litigation claim was logically connected to Braintree’s infringement action such that it was properly considered a compulsory counterclaim.⁹ *Fed. R. Civ. P.* 13(a)(1)(A); see also *Jarrow Formulas, Inc. v. Int’l Nutrition Co.*, 175 F. Supp. 2d 296, 308 (D. Conn. 2001) (citing *Critical-Vac*, 233 F.3d at 703-04)). Although Rule 13(a) does not require a defendant to file as a compulsory counterclaim a claim that has not yet accrued, see, *gen.*, *Allan Block Corp. v. Cty. Materials Corp.*, 512 F.3d 912, 920 (7th Cir. 2008) (collecting cases), several courts considering the issue have held that sham litigation claims accrue when the case is filed. See *Al George, Inc. v. Envirotech Corp.*, 939 F.2d 1271, 1275 (5th Cir. 1991); *P&M Services, Inc. v. Gubb*, Civ. No. 07-12816, 2008 WL 4185903, *6 (E.D. Mich. Sept. 8, 2008), *aff’d*, 372 Fed. Appx. 613 (6th Cir. 2010).

⁹Had Schwarz not pled sham litigation as a counterclaim in the original action, the claim could not have been raised in a subsequent suit. See *Critical-Vac*, 233 F.3d at 699 (citing *Baker v. Gold Seal Liquors, Inc.*, 417 U.S. 467, 469 n.1 (1974)).

The foregoing dispatches MMOH's argument that its sham litigation claims did not accrue until July 31, 2008, when the court published its opinion concluding the Braintree/Schwarz litigation. (D.I. 13 at 12) While there is one district court that has adopted this view, it did so in distinguishable circumstances. See *Chemi SpA*, 356 F. Supp. 2d at 500 (holding that antitrust claims accrued on the date of the court's opinion that defendant procured the patent on its branded drug through fraudulent representations to the PTO and that the patent was unenforceable). This court did not find in favor of Schwarz on July 31, 2008; judgment instead was entered for Braintree as the court found that Schwarz did not meet its high burden of proving objective baselessness. Therefore, the July 31, 2008 opinion did not provide any confirmation regarding the merits of MMOH's potential claims against Braintree.¹⁰

To hold otherwise would ignore that a plethora of information evaluated by the court in connection with the Braintree/Schwarz litigation – for example, the '183 patent and its prosecution history – was publicly available prior to the court's 2008 opinion. Indeed, MMOH does not specifically iterate what information was not available to it prior to 2008. See *Molecular Diagnostics Labs. v. Hoffman-La Roche Inc.*, 402 F. Supp. 2d 276, 284-85 (D.D.C. 2005) (where court's findings in 2004 mirrored those made in 1999, notice was deemed provided on the earlier date as "no remaining pieces of the puzzle needed to be discovered"). Moreover, to the extent Braintree's (allegedly inconsistent and objectively baseless) positions on the '183 patent were not

¹⁰Braintree points out that the *Chemi SpA* court did not cite any judicial authority for the proposition that "an antitrust claim based on baseless litigation **requires proof** that the litigation was unsuccessful, which can only be determined upon the termination of the initial action." *Chemi SpA*, 356 F. Supp. 2d at 500 (emphasis added).

ascertainable from public pleadings filed as early as 2003, they were exposed at trial between January 29 and February 2, 2007.¹¹

In view of the foregoing, the complained-of act vis a vis MMOH's sham ANDA litigation claim generally would be the filing of the underlying suit against Schwarz by Braintree on May 16, 2003. See *In re Relafen Antitrust Litig.*, 286 F. Supp. 2d 56, 61-62 (D. Mass. 2003). There are two possible exceptions to the tolling of this accrual date: (1) if Braintree committed a "continuing violation of the Sherman Act" inflicting continuing and accumulating harm; or (2) if damages flowing from Braintree's alleged anticompetitive conduct were unascertainable at the time Braintree engaged in such conduct. *Zenith Radio Corp.*, 401 U.S. at 338-39 (citations omitted). In a factually analogous situation, the United States District Court for the District of Massachusetts concluded that the act of merely "[c]ontinuing to litigate a sham law suit does not constitute a 'continuing violation' of the antitrust laws." *In re Relafen Antitrust Litig.*, 286 F. Supp. 2d at 62. MMOH, like plaintiffs in the *Relafen* litigation, did not allege a "series of discrete acts of predatory pricing" or an enduring price-fixing conspiracy such as might constitute a continuing violation. *Id.*; (D.I. 1 at ¶¶ 97, 114) Therefore, there is no continuing violation exception to the running of the statute of limitations in this case.¹²

¹¹Schwarz asserted its sham litigation counterclaim in 2003. MMOH implies that it could not be fully aware of the details of the Braintree/Schwarz litigation as "nearly everything [was] filed under seal." (D.I. 13 at 11) MMOH does not argue that it was not aware of the filing of the Braintree/Schwarz litigation, only that the success of Braintree's allegedly baseless claims could not be ascertained until the court's decision. (*Id.* at 9) The court notes further that the Braintree/Schwarz trial transcript was made part of the public record in February 2007.

¹²MMOH's argument that the statute of limitations issue is not ripe because it is unclear on what date recoverable overcharge damages **ceased** (i.e., there is a

“The cause of action for future damages [accrues] only on the date they are suffered[.]” *Zenith Radio Corp.*, 401 U.S. at 339. In this regard, the *In re Relafen Antitrust Litigation* court found that the speculative damages exception applied to toll plaintiffs’ accrual date from the date of the filing of the allegedly sham ANDA litigation to the date the first tentative approval was received by a generic competitor. 286 F. Supp. 2d at 63-64. The court reasoned that, prior to this point, damages are “entirely speculative” since it is unclear “whether the FDA itself would even approve [] competitors” in the first instance. *Id.* at 63. The *In re Relafen Antitrust Litigation* court also noted the “absurd result” that would occur absent the application of the exception, as “vast numbers of potential antitrust plaintiffs would be required in every patent or business litigation to sue or intervene preemptively in those actions in the unlikely (but possible) event that the suit was filed fraudulently.” *Id.* at 64. The court finds this reasoning convincing and holds that MMOH’s claims accrued no later than December 23, 2003 – the date Schwarz received tentative approval to sell GlycoLax®. (D.I. 1 at ¶ 76)¹³

B. Application of the Statute of Limitations

The question before the court at this juncture is whether MMOH’s claims are untimely on the face of its complaint. *See Oshiver v. Levin, Fishbein, Sedran & Berman*, 38 F.3d 1380, 1385 n. 1 (3d Cir. 1994) (cautioning the decision of the statute

“damages tail”) is, therefore, moot.

¹³Braintree acknowledges in this case that plaintiffs’ claims did not accrue when the Braintree/Schwarz litigation was filed “because prior to that point Schwarz could not have received final FDA approval . . . and therefore there would have been no ‘overcharge’.” (D.I. 16 at 3 & n.2)

of limitations in the context of a Rule 12 motion, except in situations where “the complaint facially shows noncompliance with the limitations period and the affirmative defense clearly appears on the face of the pleading”). As noted previously, MMOH brings claims for violations of state antitrust, consumer fraud and unjust enrichment laws. In these regards, Delaware’s Borrowing Statute, 10 Del. C. § 8121, requires the court to apply the shorter of Delaware’s statute of limitations (three years¹⁴) or the statute of limitation of the state in which the claim arose. In all instances, therefore, the applicable statute of limitations is three years or less.¹⁵

The court rejects MMOH’s argument that the Delaware Borrowing Statute does not apply because Braintree is a “forum shopper,” having elected to sue Schwarz in Delaware in the underlying litigation. (D.I. 13 at 6) While MMOH argues that it was bound to litigate here, since this was the Braintree/Schwarz litigation forum and because the PFTH&W litigation was transferred here in 2007, that argument is not supported by any failed attempt by MMOH to litigate elsewhere. Had MMOH filed in another district and its case transferred to this court, the transferor’s choice of law rules would have applied. See *Ferens v. John Deere Co.*, 494 U.S. 516, 523 (1990) (“A transfer under § 1404(a) . . . does not change the law applicable to a diversity case”). Notwithstanding, the court declines to hold that Braintree sued Schwarz in Delaware in 2003 in order to secure this venue (and its statute of limitations) for multiple future

¹⁴See 6 Del. C. § 2111 (antitrust); 6 Del. C. § 8106 (unjust enrichment and unfair competition).

¹⁵Braintree has provided an index of MMOH’s claims with citations to the corresponding state statute of limitations for each claim. (D.I. 11 at 1) MMOH does not dispute Braintree’s representations.

antitrust lawsuits against it.

Finally, the parties agree that the running of the statute of limitations should toll in this case based on the time the PFTH&W litigation was pending.¹⁶ (D.I. 11 at 12-13; D.I. 13 at 8) That is, the running of the statute of limitations in this case tolls for two years, one month and 23 days. (*Id.*) The calculations are as follows:¹⁷

MMOH filed its complaint	July 14, 2010
Accrual date	December 23, 2003

Difference	6 years, 6 months and 21 days
Subtract tolled period	- 2 years, 1 month and 23 days

	4 years, 4 months and 29 days

Alternatively,

Accrual date	December 23, 2003
Add three year SOL	December 23, 2006
Add tolled period	+ 2 years, 1 month and 23 days

	February 15, 2009

As the foregoing indicates, MMOH's claims, filed July 14, 2010, or 4 years, 4 months and 29 days from the date of tentative FDA approval on GlycoLax® on December 23,

¹⁶Under Federal law, "the commencement of a class action suspends the applicable statute of limitations as to all asserted members of the class who would have been parties had the suit been permitted to continue as a class action." *American Pipe & Construction Co. v. Utah*, 414 U.S. 538, 554 (1974). "Once the statute of limitations has been tolled, it remains tolled for all members of the putative class until class certification is denied." *Crown, Cork & Seal Co., Inc. v. Parker*, 462 U.S. 345, 353-54 (1983). The PFTH&W litigation was voluntarily dismissed on June 2, 2009, prior to any denial of class certification.

¹⁷The court garners assistance from the date calculator supplied at <http://www.timeanddate.com> in these regards.

2003, are untimely under even a three-year statute of limitations.¹⁸

V. CONCLUSION

For the foregoing reasons, Braintree's motion to dismiss is granted. An appropriate order shall issue.

¹⁸The court need not reach Braintree's alternative grounds for dismissal.